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Guidance for Industry

How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

Final Guidance

This final guidance describes how to use e-mail to submit Notices of Intent to Slaughter for Human Food Purposes (slaughter notices) to the Center for Veterinary Medicine (CVM or the Center) and the U.S. Department of Agriculture (USDA).

E-mail submissions that follow this final guidance will be compatible with CVM's current information technology capabilities. This will help ensure the confidentiality, integrity, security, and authenticity of data submitted to the Center. If a regulated company or person wishes to use an electronic approach other than that set forth in this guidance document, the Center will, on request, discuss alternative methods of submitting slaughter notices.

Comments and suggestions regarding this document should be sent to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fisher's Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 00D-1314.

For questions regarding this final document, contact Janis R. Messenheimer, Center for Veterinary Medicine, (HFV-135), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7578, E-mail: jmessenh@cvm.fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
February 1, 2001

00D-1314

GDL 2

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GUIDANCE FOR INDUSTRY[1]

HOW TO USE E-MAIL TO SUBMIT A SLAUGHTER NOTICE

This final guidance represents FDA's current thinking on this matter. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used as long as it satisfies the requirements of the applicable statute and regulations.

I. BACKGROUND

Section 512(j) of the Federal Food, Drug, and Cosmetic Act gives FDA the authority to issue regulations setting out the conditions for marketing animals treated with investigational new animal drugs for food use. Under this authority, FDA's regulations at 21 CFR 511.1(b)(4) provide that sponsors must obtain authorization to slaughter these animals for food. Under 21 CFR 511.1(b)(5), CVM issues a slaughter authorization letter to new animal drug sponsors (sponsors) which sets the terms under which animals treated with investigational new animal drugs may be slaughtered. USDA also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act, 21 U.S.C. 601-95. To assist CVM and USDA with this monitoring, the authorization letter states that sponsors must submit slaughter notices each time such animals are to be slaughtered unless CVM waives this notice in the authorization letter. Currently, slaughter notices are submitted to CVM and USDA on paper. This guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by the Internet.

The electronic submission of slaughter notices is part of the Center's ongoing initiative to provide a method for paperless submissions.

This final guidance implements provisions of the Government Paperwork Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681 (1998), which requires that executive agencies, by October 21, 2003, provide: (1) for the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures when practicable.

This final document contains specific instructions for submitting slaughter notices. Guidance #108, How to Use E-Mail to Submit Information to CVM, contains general instructions and specifications on submitting information electronically to CVM by e-mail. It is available on the CVM Home Page. Sponsors should first register and

[1] This final guidance and form have been prepared by CVM at FDA. For additional copies of this final guidance and form, access the document on the Internet by connecting to the CVM Home Page at http://www.fda.gov/cvm, or send a request to the Communications Staff, HFV-12, 7500 Standish Place, Rockville, MD 20855.

follow the instructions in guidance #108 before submitting slaughter notices as an e-mail attachment.

II. CHECKLIST FOR SUBMITTING A SLAUGHTER NOTICE USING ADOBE®ACROBAT® 4.0[2]

A sponsor submitting an electronic slaughter notice should send the notice as a single Portable Document Format (PDF) file attached to an e-mail. This checklist describes the process sponsors should follow to create a PDF file using a word processing program, print it to the Acrobat® Distiller, and submit the information. The PDF file can be created using other software.

1. Use a word processing software package to create a document following the form and containing the information requested in Section III.
2. Make sure Acrobat® Distiller is selected as the default printer.
3. Fill in all pertinent sections of the slaughter notice FDA Form #3488.
4. Print the word processing document to Acrobat® Distiller to create a PDF file.
5. Name the PDF file using an 8.3 file naming convention. Save the PDF file in the appropriate directory location and close the file.
6. Open the PDF file in Adobe® Acrobat® 4.0, select "Save As" and select the "Security" options for "Specify Password To: Open the Document". Enter your password and click OK. Verify the password by entering it again and then "Save" the PDF file.
7. Open your e-mail program and begin a new message.
8. Address it to cvmdcu@cvm.fda.gov and manzoor.chaudry@usda.gov.
9. Type the nine character word **SLAUGHTER** in the subject line, using all capital letters. Do not include any other punctuation or information in the subject line.
10. Do not type anything in the body of the message.
11. Attach the PDF file of the slaughter notice to the e-mail message.
12. Send the e-mail message.
13. If you have not received an acknowledgment receipt from CVM (stars@cvm.fda.gov) within three business days after you have sent the submission, call the Electronic Document Control Unit at 301-827-8277 to report the problem and find out what happened to your submission.

Sponsors are requested to submit their slaughter notification to FDA and USDA **at least 10 days prior** to shipment for slaughter unless conditions outlined in the authorization letter provide otherwise.

[2] This checklist uses Adobe Acrobat 4.0 for the purpose of example. FDA use of specific products does not constitute endorsement of those products. Sponsors may use other software to create files.

III. NOTICE OF INTENT TO SLAUGHTER FOR HUMAN FOOD PURPOSES FORM

A copy of the FDA Form #3488 for electronic Notice of Intent to Slaughter for Human Food Purposes follows.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine	**Notice of Intent to Slaughter for Human Food Purposes**	Form Approved: OMB No. 0910-0450 Expiration Date: 11/30/2003

PAPERWORK REDUCTION ACT STATEMENT: A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control Number. The public reporting burden for the collection of information is estimated average 25 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary information, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Food and Drug Administration, Center for Veterinary Medicine, HFV-6, 7500 Standish Place, Rockville, MD 20855.

Submit this notice electronically to:
Food and Drug Administration
Center for Veterinary Medicine (HFV-)
7500 Standish Place
Rockville, Maryland 20855
(E-mail:cvmdcu@cvm.fda.gov)

DATE:
INAD / IFA NO:
STUDY / TRIAL ID:

The sponsor, , submits a notice of intent to slaughter animals treated with investigational new animal drugs according to the conditions of authorization, CVM letter dated and, **at least 10 days prior to slaughter.** This information is submitted in electronic form to CVM and USDA.

I. Animals Intended For Slaughter

1. NAME(S) OF THE DRUG(S)

   Established name(s):

   Trade name(s):
2. SPECIES OF ANIMALS:
3. NAME AND ADDRESS OF INVESTIGATOR:

4. NAME AND ADDRESS OF SLAUGHTER FACILITY:

   ESTABLISHMENT NUMBER:
5. NUMBER OF ANIMALS BEING SLAUGHTERED:
   Total: Treated: Control:
6. APPROXIMATE DATE OF SLAUGHTER:
7. LENGTH OF WITHDRAWAL PERIOD OBSERVED:
8. COMMENTS:

II. Sponsor Information

1. SPONSOR'S NAME:
2. SPONSOR'S ADDRESS:

3. SPONSOR CONTACT'S NAME:
4. SPONSOR CONTACT'S PHONE NUMBER:
5. SPONSOR CONTACT'S FAX NUMBER:
6. SPONSOR CONTACT'S E-MAIL ADDRESS: